

**Maryland Board of Pharmacy  
Public Board Meeting**

**Agenda  
November 21, 2018**

Name		Title	Present	Absent
Ashby, D.		Commissioner		
Bouyoukas, E		Commissioner		
Evans, K.		Commissioner		
Hardesty, J.		Commissioner/Treasurer		
Laws Jr, A.		Commissioner		
Leikach, N.		Commissioner		
Morgan, K.		Commissioner/President		
Oliver, B		Commissioner		
Peters, R.		Commissioner		
Rusinko, K.		Commissioner		
Toney, R.		Commissioner/Secretary		
Yankellow, E.		Commissioner		
Bethman, L.		Board Counsel		
Felter, B.		Staff Attorney		
Speights-Napata, D.		Executive Director		
Fields, E.		Deputy Director /Operations		
Evans, T.		Compliance Director		
Brand, E.		Licensing, Legislation and Regulations Manager		
Chew, C.		Management Associate		
<b>I. Executive Committee Report(s)</b>	<b>A.) K. Morgan, Board President</b>	<i>Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.</i>		

November 21, 2018

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
	B.) R. Toney, Secretary	<ol style="list-style-type: none"> <li>1. Call to Order</li> <li>2. Sign-in Introduction and of meeting attendees – (Please indicate on sign-in sheet if you are requesting CE Units for attendance)</li> <li>3. Distribution of Agenda and packet materials</li> <li>4. Review and approve October 2018 Public Meeting Minutes</li> </ol>	
II. A. Executive Director Report	D. Speights-Napata, Executive Director	<ol style="list-style-type: none"> <li>1. Operations Updates</li> <li>2. Meetings Update</li> </ol> <p>New Board Commissioner Welcome--Kristopher Rusinko—Kevin</p> <p>MD Health Care Commission Electronic Submission Workgroup--Jennifer</p> <p>American Society for Pharmacy Law Meeting--Linda</p> <p>Notre Dame School of Pharmacy Licensing meeting—Etzion</p> <p>Contraception Forms--Etzion</p>	
B. Operations	E. Fields, Deputy Director/Operations	<ol style="list-style-type: none"> <li>1. Procurement and Budget Updates               <ol style="list-style-type: none"> <li>a: October 2018 Financial Statements</li> <li>b: UMAB Survey</li> <li>c: Systems Automation Enhanced Services</li> </ol> </li> <li>2. Management Information Systems (MIS) Unit Updates               <ol style="list-style-type: none"> <li>a: Systems Automation Enhanced Services</li> </ol> </li> </ol>	

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<b>C. Licensing</b>	<b>E. Brand, Licensing, Legislation and Regulations Manager</b>	<b>1. Unit Updates</b> <b>2. Monthly Statistics</b>					
		License Type	New	Renewed	Reinstated	Total	
		Distributor	21	0	0	1,310	
		Pharmacy	13	0	0	2,105	
		Pharmacist	104	473	0	12,001	
		Vaccination	63	28	0	4,669	
		Pharmacy Intern - Graduate	1	0	0	44	
		Pharmacy Intern - Student	14	17	0	911	
		Pharmacy Technician	103	288	5	9,800	
		Pharmacy Technician-Student	3	0	0	13	
		<b>TOTAL</b>	322	806	5	30,853	
<b>D. Compliance</b>	<b>T. Evans, Compliance Director</b>	<b>1. Unit Updates</b> <b>2. Monthly Statistics</b> <b>Complaints &amp; Investigations:</b>					

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		<p>New Complaints - 47</p> <ul style="list-style-type: none"> <li>• Child Support - 2</li> <li>• Disciplinary Actions in Another State - 6</li> <li>• Medication Error - 3</li> <li>• Billing Error - 1</li> <li>• Reimbursement compliant - 1</li> <li>• Inspection Issues - 27</li> <li>• Refusal to Fill-2</li> <li>• Customer Service-1</li> <li>• Unprofessional Conduct-2</li> <li>• Shipping without a Permit-1</li> <li>• HIPPA Violation-1</li> </ul> <p>Resolved (Including Carryover) – 50  Actions within Goal – 19/50  Final disciplinary actions taken – 7  Summary Actions Taken – 0</p> <p><b>Inspections:</b></p> <p>Total - 129  Annual Inspections -111  Opening Inspections -7  Closing Inspections -4  Relocation/Change of Ownership Inspections -2  Board Special Investigation Inspections - 5</p>	
<b>E. Legislation &amp; Regulations</b>	<b>E. Brand, Legislation and Regulations Manager</b>	<p><u><b>Regulations</b></u></p> <p><u>COMAR 10.34.32.03 D Requirements to Administer Vaccinations</u></p>	

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		<u>Proposed COMAR 10.34.05.05 Security Responsibilities</u> <u>COMAR 10.34.30 Applications</u> <u>Proposed COMAR 10.34.09 Fees</u> <u>Contraceptive Prescription Forms</u> <u>Legislation</u> <u>Generic Substitution Revision 12-504</u>	
<b>III. Committee Reports</b>  <b>A. Practice Committee</b>	<b>R. Peters, Chair</b>		
	<b>Opeoluwa Fagbemi</b>	<p>I am a licensed pharmacist in Maryland. I am interested in engaging my local community church and nursing homes to offer flu shots. I would like to know what the board requires for me to maintain compliance. For example, I want to independently purchase flu shots, store them appropriately, and immunize my local church and engage local nursing homes. Since I do not own a pharmacy, and so do not have an NPI# or contract with insurance/ a processing software for claims, I wanted to know what steps, if possible, and/ or compliance I would need in order to serve my community while educating them on the importance of getting immunized.</p>	<p>Proposed response:</p> <p>You may administer vaccines off-site under the authority of your pharmacist's license. However, you must comply with the regulations for registration to administer, and the reporting, recordkeeping and protocol requirements of COMAR 10.34.32</p>

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09/13/2018	<b>Rotimi Fagbemi</b>	<p>My name is Rotimi Olawale Fagbemi, holder of Maryland Pharmacist license #23198. I have the desire to operate an online pharmacy based in the state of Maryland but specifically designed for patients outside of the United State of America.</p> <p>The main purpose of this is to serve patients with valid prescriptions from hospitals and health institutions from their countries of residence while in need of pharmaceutical products from the United States of America. For example, I practice pharmacy for about two decades in Nigeria before coming to United States of America and I noticed that many patients are sometimes in need of pharmaceutical products from America without knowing how to go about it.</p> <p>I hereby require from your board what you will want me to do in order to meet the compliance as to obtain this noble and special license. Should I be given the opportunity, I promise to professionally and dutifully follow the compliance accordingly.</p>	<p>Proposed response:</p> <p>The Board of Pharmacy does not authorize pharmacies to fill prescriptions written by prescribers outside the United States.</p>
10/12/2018	<b>Jerad Pasay</b>	<p>During a follow-up inspection it was observed that a pharmacy is filling prescriptions and all refills of sterile compounded Avastin for ophthalmic use at once, per doctor's requests.</p> <p>As per the Pharmacy PIC regarding prescription dispensing and refills: "Pharmacy gets an order pursuant to a prescription and dispenses prescription to the Doctor for patient administration at the administration site (at Doctors Office). IN ONLY THESE INSTANCES as per the Doctors request a new prescription and refills will be requested all at once and dispensed accordingly."</p> <p>In accordance with HO §12-403(22) A pharmacy:</p> <p>"(ii) May provide to an ophthalmologist for office use, without a patient-specific prescription:</p> <ol style="list-style-type: none"> <li>1. Compound antibiotics for the emergency treatment of bacterial endophthalmitis or viral retinitis; and</li> <li>2. Compound antivascular endothelial growth factor agents for the emergency treatment of neovascular glaucoma, wet macular degeneration, or macular edema; and</li> </ol> <p>(ii) Shall require the ophthalmologist to inform the pharmacy of the identity of any patient to whom the drugs are administered."</p>	<p>Proposed response:</p> <p>A compounding pharmacy may provide to an ophthalmologist for <u>office use</u>, without a patient –specific prescription: Compounded antivascular endothelial growth factors agents for emergency treatment of neovascular glaucoma, wet macular degeneration, or macular edema. The pharmacist does not need to have a prescription with multiple refills under the office use provision. The process under office use supplied drug is to have the ophthalmologist place an order for the drug for office use. The ophthalmologist shall inform the pharmacy of the identity of any patient to whom the drug is administered.</p>

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		<p>Avastin is used, off label, by Ophthalmologists in the treatment of macular degeneration by blocking the growth of new abnormal blood vessels in the macula of the eye. Treatment is repeated as needed at 4 to 6 week intervals.</p> <p>Is filling prescriptions and refills all at once an appropriate pharmacy practice? Is it appropriate for this type of medication? Is this practice even required for this medication given the allowances provided in HO §12-403(22)? Would dispensing prescriptions and refills all at once lead to doctors misusing prescription medication as office use?</p>	
10/12/2018	Bob Gadani	<p>We at the pharmacy level are getting increasing queries as to if we carry and sell CBD products. Quarterfinal Pharmacy is contemplating ordering the product from our wholesaler and concurrently doing its own research on the compliance of selling CBD products as it relates to the Pharmacy laws in the state of Maryland and compliance with Controlled Substance ACT. What we have found is the following:</p> <ol style="list-style-type: none"> <li>1. Maryland House Bill 803 which dealt with the agriculture, criminal and legalization of Industrial Hemp was Approved by Governor Hogan in May 2015.</li> <li>2. In a Senate hearing on June 24, 2015, it was mentioned that "CBD derived from cannabis plant is controlled under schedule 1 of the CSA" (see attached). The CBD products that our wholesaler is carrying is from the Hemp plant, which was legalized in Maryland by the previous mentioned Bill. On the DEA website it does not have the classification of CBD derived from the HEMP plant.</li> <li>3. We could not find any guidance as to Cannabidiol products in COMAR 10.62</li> <li>4. A law firm has done research on the legality of CBD as it relates to the Controlled Substance Act, on behalf of the company whose CBD products our wholesaler will carry. (Please see attached).</li> <li>5. Certificate of Essay showing lack of and detectable THC is available on any CBD products carried by our wholesaler.</li> <li>6. Pain clinic physicians are actively promoting CBD as an</li> </ol>	<p>Proposed response:</p> <p>CBD is listed as a Schedule I substance under federal law. The DEA's position is to treat it as a Schedule I substance regardless of conflicting state law.</p>

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		<p>alternative option to opioids.</p> <p>7. Maryland residents can freely get CBD online or from non-pharmacy sources</p> <p>8. Our Wholesaler, Value Drug, is asking for a retail pharmacy agreement signed by the pharmacy before any CBD products can be ordered. (see attached)</p> <p>Based on the above Quarterfield Pharmacy is asking for guidance from the Maryland Board of Pharmacy on being able to order and sell CBD products at the retail pharmacy level.</p>	
10/24/2018	Thomas Evans	<p>The practice committee recommended that the draft of the MOU should go before the full Board and the public for discussion and comment before 12/10/2018, the close of public comment.</p>	<p>Proposed comment:</p> <p>The requirement for the state boards of pharmacy to report adverse events and interstate distribution (dispensing) of 50% or greater should be limited to sterile compounded products only for 503A facilities. The potential safety issues associated with Non-sterile compounded products does not rise to the same level as sterile compounded products and the collection and reporting of these statistics would be burdensome to both pharmacies and boards of pharmacy.</p>
B. Licensing Committee	D. Ashby, Chair	<ol style="list-style-type: none"> <li>1. Review of Pharmacist Applications: NONE</li> <li>2. Review of Pharmacy Intern Applications: NONE</li> <li>3. Review of Pharmacy Technician Applications: NONE</li> <li>4. Review of Distributor Applications: NONE</li> <li>5. Review of Pharmacy Applications: <ol style="list-style-type: none"> <li>a. HHI Infusion Services LLC - Company is requesting the Board reconsider its prior denial</li> </ol> </li> </ol>	



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		<p>which was based on the fact that the pharmacy is owned by doctors.  <i>Licensing Committee's Recommendation: Deny</i></p> <p><b>6. Review of Pharmacy Technicians Training Programs: NONE</b></p> <p><b>7. New Business:</b></p> <p>a. <b>L.M.</b> - Registrant is requesting that the Board send the hours earned working as a Technician to the DC Board of Pharmacy as Intern hours.  <i>Licensing Committee's Recommendation: Deny</i></p> <p>b. <b>Maria Eng</b> - Requests approval of CEs  <i>Licensing Committee's Recommendation: Deny</i></p>	
<b>C. Public Relations Committee</b>	<b>E. Yankellow, Chair</b>	<b>Public Relations Committee Update:</b>	
<b>D. Disciplinary</b>	<b>K. Morgan, Chair</b>	<b>Disciplinary Committee Update</b>	
<b>E. Emergency Preparedness Task Force</b>	<b>N. Leikach, Chair</b>	<b>Emergency Preparedness Task Force Update</b>	
<b>IV. Other Business &amp; FYI</b>	<b>K. Morgan, President</b>		
<b>V. Adjournment</b>	<b>K. Morgan, President</b>	<p><b>A. The Public Meeting was adjourned.</b></p> <p><b>B. K. Morgan convened a Closed Public Session to conduct a medical review committee evaluation of confidential applications.</b></p>	

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		<p><b>C. The Closed Public Session was adjourned. Immediately thereafter, K. Morgan convened an Administrative Session for purposes of discussing confidential disciplinary cases.</b></p> <p><b>D. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Closed Public Session and the Administrative Session.</b></p>	